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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Philip L. Camillocci et al.

Serial No.: 10/706,197

Filed: November 12, 2003

For: ENDOSCOPE COVER

§ Group Art Unit: 3739

§ Examiner: Kasztejna, Matthew John

§ Atty. Docket: 132387-1/YOD
GEMS:0230

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Helen Tinsley

Helen Tinsley

APPEAL BRIEF PURSUANT TO 37 C.F.R. §§ 41.31 AND 41.37

This Appeal Brief is being filed in furtherance to the Notice of Appeal mailed on March 13, 2007, and received by the Patent Office on March 19, 2007.

The Commissioner is authorized to charge the requisite fee of \$500.00, and any additional fees which may be necessary to advance prosecution of the present application, to Account No. 50-2401; Order No. 132387IT/YOD (GEMS:0230).

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1. **REAL PARTY IN INTEREST**

The real party in interest is GE Medical Systems Information Technologies, Inc., the Assignee of the above-referenced application by virtue of the Assignment to GE Medical Systems Information Technologies, Inc., a subsidiary of General Electric Company, recorded at reel 014701, frame 0113, and dated November 12, 2003. Accordingly, General Electric Company, as the parent company of the Assignee of the above-referenced application, will be directly affected by the Board's decision in the pending appeal.

2. **RELATED APPEALS AND INTERFERENCES**

Appellants are unaware of any other appeals or interferences related to this Appeal. The undersigned is Appellants' legal representative in this Appeal.

3. **STATUS OF CLAIMS**

Claims 1-5 and 7-40 are currently pending, are currently under final rejection and, thus, are the subject of this Appeal.

4. **STATUS OF AMENDMENTS**

There are no outstanding amendments to be considered by the Board.

5. **SUMMARY OF CLAIMED SUBJECT MATTER**

The present invention relates generally to the field of endoscopes. More particularly, the invention relates to a technique for identifying and protecting a probe portion of an endoscope. *See, Application, page 1, lines 4-6.*

The Application contains seven independent claims, namely, claims 1, 8, 15, 22, 27, 31 and 36, all of which are the subject of this Appeal. The subject matter of these claims is summarized below.

With regard to the aspect of the invention set forth in independent claim 1, discussions of the recited features of claim 1 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with claim 1 provides a cover for use with an endoscope, comprising a body (e.g., 34) having a recessed portion (e.g., 44) configured to releasably secure to an insertion portion of the endoscope (e.g., 16). *See, e.g., id.* at page 5, line 9; page 8, lines 24; page 10, line 28; page 22, lines 23-25; *see also* Figs. 1-2. The cover further comprises a disinfecting compound disposed thereon, wherein the body (e.g., 34) is configured to be disposed on the tip of the endoscope only when the endoscope is not in use. *See, e.g., id.* at page 11, line 17 – page 12, line 2; *see also* Fig. 2.

With regard to the aspect of the invention set forth in independent claim 8, discussions of the recited features of claim 8 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with claim 8 provides a cover for use with an endoscope, comprising a body (e.g., 34) having a recessed portion (e.g., 44) configured to releasably secure to a probe portion of the endoscope (e.g., 16). *See, e.g., id.* at page 5, line 9; page 8, lines 24; page 10, line 28; page 22, lines 23-25; *see also* Figs. 1-2. Further, the body includes an indicium (e.g., 50) configured to indicate a condition of the endoscope, wherein the body (e.g., 34) is configured to be disposed on the tip of the endoscope only when the endoscope is not in use. *See, e.g., id.* at page 11, line 17 – page 12, line 2; *see also* Fig. 2.

With regard to the aspect of the invention set forth in independent claim 15, discussions of the recited features of claim 15 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with claim 15 provides an endoscope system (e.g., 10) comprising an endoscope (e.g., 16). The endoscope comprises a light source (e.g., 36) configured to produce a light beam, and a flexible conduit (e.g., 22) having a probe end (e.g., 24) and configured to receive the light beam from the light source. *See, e.g., id.* at page 6, lines 9-21; *see also* Fig. 1. Further, the flexible conduit is configured to direct the light beam

outwardly with respect to the probe end. *See, e.g., id.* at page 9, lines 4-16. The endoscope system further comprises first and second cover members (*e.g.*, 34, 35) each having a recessed portion (*e.g.*, 44) configured to releasably secure to the probe end. *See, e.g., id.* at page 5, line 9; page 8, lines 24; page 10, line 28; page 22, lines 23-25; *see also* Figs. 1-2. Further, the first cover member comprises a first indicium indicative of a first endoscope condition and the second cover member comprises a second indicium indicative of a second endoscope condition. *See, e.g., id.* at page 8, lines 21-28; *see also* Fig. 2. The first and second cover members (*e.g.*, 34, 35) are configured to be disposed on the tip (*e.g.*, 24) of the endoscope only when the endoscope is not in use. *See, e.g., id.* at page 11, line 17- page 12, line 2.

With regard to the aspect of the invention set forth in independent claim 22, discussions of the recited features of claim 22 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with claim 22 provides a method of covering a probe portion of an endoscope. The method comprises securing (*e.g.*, 70) a first cover member (*e.g.*, 34) having a first indicium indicative of a first endoscope condition to the probe portion (*e.g.*, 24), and removing (*e.g.*, 60) the first cover member from the probe portion. *See, e.g., id.* at page lines 1-28; *see also* Fig. 5. The method further comprises securing (*e.g.*, 64) a second cover member (*e.g.*, 35) having a second indicium indicative of a second endoscope condition to the probe portion, wherein the first and second cover members are configured to be disposed on the tip of the endoscope only when the endoscope is not in use. *See, e.g., id.* at page 11, line 17- page 12, line 2; page 14, lines 1-4; *see also* Fig. 5.

With regard to the aspect of the invention set forth in independent claim 27, discussions of the recited features of claim 27 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with claim 27 provides an endoscope system comprising an endoscope (*e.g.*, 16) including a flexible conduit (*e.g.*, 22) having a probe portion (*e.g.*, 24). *See, e.g., id.* at page 6, lines 9-21; *see also* Fig. 1. The endoscope further comprises a first means (*e.g.*,

34) for covering the probe portion, thereby indicating a first status of the endoscope, and a second means (e.g., 35) for covering the probe portion thereby indicating a second status of the endoscope. *See, e.g., id.* at page 8, lines 21-28; *see also* Fig. 2. Further, the first and second means (e.g., 34, 35) are configured to be disposed on the tip of the endoscope only when the endoscope is not in use. *See, e.g., id.* at page 11, line 17- page 12, line 2.

With regard to the aspect of the invention set forth in independent claim 31, discussions of the recited features of claim 31 can be found at least in the below cited locations of the specification and drawings: By way of example, an embodiment in accordance with claim 31 provides a method of manufacturing a cover for a probe portion of an endoscope. The method comprises shaping a flexible synthetic material to form a cover (e.g., 34) configured to releasably secure to the probe portion. *See, e.g., id.* at page 8, lines 24-25; page 10, lines 21-27; *see also* Fig. 2. The method further comprises integrating with respect to the cover an indicium (e.g., 50) indicative of a status of the endoscope, wherein the cover is configured to be disposed on the tip of the endoscope only when the endoscope is not in use. *See, e.g., id.* at page 11, line 17- page 12, line 2; lines 4-7; *see also* Fig. 2.

With regard to the aspect of the invention set forth in independent claim 36, discussions of the recited features of claim 36 can be found at least in the below cited locations of the specification and drawings. By way of example, an embodiment in accordance with claim 36 provides an endoscope cover system including an endoscope having an insertion portion comprising a first cover (e.g., 34) having a first indicia indicative of a used state and a need for sterilization, the cover being configured to receive the insertion portion (e.g., 24). The endoscope cover system further comprise a second cover (e.g., 35) having a second indicia indicative of a sterilized state, the second cover being configured to receive the insertion portion, wherein the first and second covers (e.g., 34, 35) are configured to be disposed on the tip (e.g., 24) of the endoscope

only when the endoscope is not in use. *See, e.g., id.* at page 8, lines 21-28; page 11, line 17- page 12, line 2; *see also* Fig. 2.

A benefit of the invention, as recited in these claims, is the ability to protect a probe portion of an endoscope using a cover. The cover is adapted to protect sensitive components of the probe, while the endoscope and the probe are not in use. Further, the cover may include an indicium informing a clinician on the sterile condition of the probe portion, so that the clinician may ascertain whether the endoscope is suitable for use. This further reduces confusion as to whether sterilization is needed, thereby eliminating, for example, unnecessary resterilizations of the probe portion of the endoscope. This is a clear difference and distinction from the prior art, as discussed below.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

First Ground of Rejection for Review on Appeal:

Appellants respectfully urge the Board to review and reverse the Examiner's first ground of rejection in which the Examiner rejected claims 1-4 and 7 as obvious over Kieffer III et al. (U.S. Patent No. 4,380,998, hereinafter "Kieffer"), in view of a first Yabe et al. reference (U.S. Patent No. 5,514,074; hereinafter "Yabe '074").

Second Ground of Rejection for Review on Appeal:

Appellants respectfully urge the Board to review and reverse the Examiner's second ground of rejection in which the Examiner rejected claims 8-13, 15-29 and 31-40 as being obvious over Kieffer in view of Yabe et al. reference (U.S. Patent No. 5,458,133; hereinafter "Yabe '133").

Third Ground of Rejection for Review on Appeal:

Appellants respectfully urge the Board to review and reverse the Examiner's third ground of rejection in which the Examiner rejected claim 5 over Kieffer in view of Yabe '074 and further in view of Yabe '133.

Fourth Ground of Rejection for Review on Appeal:

Appellants respectfully urge the Board to review and reverse the Examiner's fourth ground of rejection in which the Examiner rejected claims 14 and 30 over Kieffer in view of Yabe '133 and further in view of Moriyama (U.S. Patent App. Pub. No. 2002/0013510; hereinafter "Moriyama").

7. ARGUMENT

As discussed in detail below, the Examiner has improperly rejected the pending claims. Further, the Examiner has misapplied long-standing and binding legal precedents and principles in rejecting the claims under Section 103. Accordingly, Appellants respectfully request full and favorable consideration by the Board, as Appellants strongly believe that claims 1-5 and 7-40 are currently in condition for allowance.

A. First Ground of Rejection

The Examiner rejected independent claim 1 over Kieffer in view of Yabe '074. Accordingly, independent claim 1 is discussed in detail below with regard to the rejection set forth by the Examiner.

1. Judicial precedent has clearly established a legal standard for a *prima facie* obviousness rejection.

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (B.P.A.I. 1979). Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching or suggestion supporting the combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). Accordingly, to establish a *prima facie* case, the Examiner must not only show that the combination includes all of the claimed elements, but also a convincing line of reason as to why one of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 U.S.P.Q. 972 (B.P.A.I. 1985). When prior art references require a

selected combination to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gained from the invention itself, i.e., something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination. *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988).

2. **The Examiner's rejection of independent claim 1 is improper because the rejection fails to establish a *prima facie* case of obviousness.**

Independent claim 1 recites:

A cover for use with an endoscope, comprising:
a body having a recessed portion configured to
releasably secure to an insertion portion of the endoscope
and;
a disinfecting compound disposed thereon, wherein
the body is configured to be disposed on the tip of the
endoscope only when the endoscope is not in use.

a. ***Kieffer Does Not Disclose a Cover Disposed on an Otoscope When the Otoscope is Not in Use***

As recited above, independent claim 1 recites a body configured to releasably secure to a probe end of an endoscope such that the body is configured to be *disposed on the tip of the endoscope only when the endoscope is not in use*. Thus, Appellants stress that the above cover is uniquely designed to be disposed on the tip of an endoscope. Moreover, the claimed cover is specifically configured to promote the sterile condition of the endoscope by being disposed on the tip of the endoscope *only when* the endoscope is not in use.

In contrast, Kieffer discloses a device specifically designed to be used on an otoscope *when in use*. Specifically, Kieffer teaches a removable speculum which contains a “rubber-like tip bounded upon the distal end thereof for protecting the ear canal and forming a seal therewith.” See, Kieffer, Abstract and Fig. 1. Thus, the otoscope cover taught by Kieffer would *only* be used during examinations, as it is intended to facilitate use of the otoscope *and* to promote patient comfort. As one of

ordinary skill in the art would appreciate, the speculum taught by Kieffer is not configured to be disposed on the tip of the otoscope only when the otoscope is not in use, as recited by the claims. Nor is the speculum taught by Kieffer even suitable or adaptable to be secured to an endoscope as claimed.

Further, in Response to Arguments, the Examiner asserted that “Kieffer *clearly shows* a cover 41 (the removable speculum) for use with an endoscope 20 (see Fig. 2).” See, Final Office Action, page 6 (Emphasis added). Appellants respectfully submit that on the contrary, there is no disclosure or suggestion in Kieffer that the speculum could or would be used with an endoscope. Appellants have challenged the Examiner to point to any teachings that the cover 41 is or could be used with an endoscope. In fact, there is not a single occurrence of the word “endoscope” in Kieffer.

The Examiner further asserted in his Response to Arguments that:

a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentable distinguish the claimed invention and the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Final Office Action, page 6.

Appellants submit that there are stark structural distinctions between endoscopes and otoscopes, rendering a clear structural distinction, as well, between the claimed endoscope cover and the speculum taught by Kieffer. The speculum taught by Kieffer is *incapable* of performing the intended use of the claimed endoscope cover. Therefore, the same reasoning used by the Examiner, *a contrario*, would lead to the conclusion that because the structure disclosed by the prior art is incapable of performing the intended use, then the prior art does not teach the structure recited in the claim. At the very least, the Examiner has provided no basis for asserting that the Kieffer speculum, even modified, would have any reasonable

likelihood of success as an endoscope cover. The Examiner has failed to establish *prima facie* obviousness for this reason alone.

a. Kieffer is Non-Analogous Art

Moreover, it is unlikely that a speculum specifically configured to be disposed on an otoscope could even be securely fitted on a probe end of an endoscope. As mentioned above, these two devices are inherently different both in their structure and functionality. In so stating, Appellants wish to reiterate, as stated in response to Office Actions, the subject matter disclosed by Kieffer is non-analogous art. Accordingly, Appellants submit that the prior art used in this case is not within the field of the inventors' endeavor. Specifically, Kieffer teaches a device apparently meant to aid clinicians specializing in medicine related to the ear, nose and/or throat. In contrast, the Appellants' endeavor is in the field of internal medicine. This is the clear field of use of an endoscope. The mere fact that the device claimed in the present patent application and the one disclosed in Kieffer are both used in the general field of medicine is insufficient to regard them as in the same field.

Further, Appellants submit that Kieffer is not reasonably pertinent to the particular problem with which the inventors are involved. The speculum taught by the cited reference is meant to protect the ear canal as it is probed. The endoscope cover presently claimed is meant to protect *an endoscope while it is not in use* and, in so doing, it properly maintains the sterile condition of the endoscope when it is not in use. Indeed, the claimed endoscope cover would never be used while the endoscope is in use. These are two very distinct problems. As one having ordinary skill in the art would appreciate, a design of a cover for an apparatus used in a medical procedure, where the cover may contact delicate organs of a human body during a procedure (as in Kieffer), is clearly distinct from a design of a cover configured to protect an apparatus, such as an endoscope, while not in use. Accordingly, Kieffer is not reasonably pertinent to the particular problem with which the inventors were involved. Accordingly, Appellants

submit, here again, that subject matter taught by the Kieffer reference is non-analogous art.

c. *Yabe '074 Does Not Disclose a Cover Disposed on an Endoscope When the Endoscope is Not in Use.*

In rejecting the claims the Examiner combined the teachings of Kieffer with the teaching of Yabe '074. However, Appellants contend that Yabe '074 teaches an endoscope cover disposed on a probe end of an endoscope *while the endoscope is in use*. That is, the reference teaches a cover disposed on an instrument insertable into a body of a patient. For example, Yabe '074 describes use of his cover by indicating that "insert part covering section 11A is taken out of the storage package of the cover (not illustrated) containing the antibacterial endoscope cover 2A." Yabe '074, col. 12, lines 4-6. Further, Yabe '074 discloses that "the insert part cover section 11A including the insert part 11B is inserted into the patient's body." Yabe '074, col. 12, 20-22; *see also* Figs. 1 and 8. Accordingly, Yabe '074 does not teach or suggest a cover configured to be disposed on the tip of a probe end of an endoscope only when the endoscope is not in use, as recited by the claims. Moreover, the Examiner did not argue, nor does Yabe '074 support the contention that the Yabe cover could or should be modified to perform as does the claimed invention.

Consequently, the combination of Kieffer and Yabe '074 clearly does not and cannot establish a *prima facie* case of obviousness of independent claim 1 or any claims depending therefrom.

In view of the arguments presented above, Appellants request the Board to reverse the rejection of independent claim 1 and those claims depending therefrom.

B. Second Ground of Rejection

The Examiner rejected independent claims 8, 15, 22, 27, 31 and 36 over Kieffer in view of Yabe '133. Each of these independent claims is discussed below.

1. **Recitations of the claims.**

Independent claim 8 recites:

A cover for use with an endoscope, comprising:
a body having a recessed portion configured to
releasably secure to a probe portion of the endoscope,
wherein *the body includes an indicium configured to indicate
a condition of the endoscope*, wherein the body is configured
*to be disposed on the tip of the endoscope only when the
endoscope is not in use.* (Emphasis added.)

Independent claim 15 recites:

An endoscope system comprising:
an endoscope comprising:
a light source configured to produce a light beam; and
a flexible conduit having a probe end and configured
to receive the light beam from the light source, wherein the
flexible conduit is configured to direct the light beam
outwardly with respect to the probe end; and
first and second cover members each having a
recessed portion configured to releasably secure to the probe
end, wherein *the first cover member comprises a first
indicium indicative of a first endoscope condition and the
second cover member comprises a second indicium
indicative of a second endoscope condition*, wherein the first
and second cover members are configured to be disposed on
*the tip of the endoscope only when the endoscope is not in
use.* (Emphasis added.)

Independent claim 22 recites:

A method of covering a probe portion of an
endoscope, comprising:
securing a first cover member *having a first indicium
indicative of a first endoscope condition* to the probe portion;
removing the first cover member from the probe
portion; and
securing a second cover member *having a second
indicium indicative of a second endoscope condition* to the
probe portion, wherein the first and second cover members

are configured to be disposed on the tip of the endoscope only when the endoscope is not in use. (Emphasis added.)

Independent claim 27 recites:

An endoscope system, comprising:
an endoscope including a flexible conduit having a probe portion;
a first means for covering the probe portion, thereby *indicating a first status of the endoscope*; and
a second means for covering the probe portion thereby *indicating a second status of the endoscope*, wherein the first and second means *are configured to be disposed on the tip of the endoscope only when the endoscope is not in use.* (Emphasis added.)

Independent claim 31 recites:

A method of manufacturing a cover for a probe portion of an endoscope, comprising:
shaping a flexible synthetic material to form a cover configured to releasably secure to the probe portion; and
integrating with respect to the cover *an indicium indicative of a status of the endoscope*, wherein the cover *is configured to be disposed on the tip of the endoscope only when the endoscope is not in use.* (Emphasis added.)

Independent claim 36 recites:

An endoscope cover system including an endoscope having an insertion portion, comprising:
a first cover *having a first indicia indicative of a used state and a need for sterilization*, the cover being configured to receive the insertion portion; and
a second cover *having a second indicia indicative of a sterilized state*, the second cover being configured to receive the insertion portion, wherein the first and second covers *are configured to be disposed on the tip of the endoscope only when the endoscope is not in use.* (Emphasis added.)

2. **The Examiner's rejection of independent claims 8, 15, 22, 27, 31 and 36 is improper because the rejection fails to establish a *prima facie* case of obviousness.**

The Examiner rejected independent claims 8, 15, 22, 27, 31 and 36 on grounds similar to those used in the rejection of independent claim 1. That is, the Examiner maintained that the speculum of the otoscope disclosed by Kieffer is analogous to the endoscope covers recited by the independent claims. Appellants reiterate that the claimed endoscope covers are uniquely designed to be disposed on the tip of the endoscope, and that such covers are specifically configured to promote the sterile condition of the endoscope only when the endoscope is not in use. Again, the teachings of Kieffer simply do not disclose or suggest an endoscope cover and any attempts to modify those teachings to arrive at the claimed subject matter is improper, as presented in the arguments above incorporated herein by reference.

For at least these reasons, Appellants request the Board to reverse the rejections of independent claims 8, 15, 22, 27, 31 and 36 and those claims depending therefrom.

C. **Third Ground of Rejection**

With respect to the rejection of dependent claim 5 over Kieffer in view of Yabe '074 and further view of Yabe '133, Appellants submit that neither Yabe '074 (as discussed above) nor Yabe '133 cure the deficiencies of Kieffer. For example, Yabe '133 discloses "an endoscope examination is carried out by using a cover type endoscope apparatus." Yabe, col. 4, lines 52-53; *see also* Figs. 1 and 2. Hence, the cover taught by Yabe '133 is used while the endoscope is in use, i.e., the cover may be inserted into the body. In view of this, Yabe '133 clearly does not disclose or suggest a cover configured to be disposed on the tip of a probe end of an endoscope only when the endoscope is not in use, as recited by the claims. Accordingly, dependent claim 5 is based on an allowable base claim. Therefore, Appellants respectfully request the Board to reverse the rejection set forth by the Examiner and allow dependent claim 5.

D. **Fourth Ground of Rejection**

With respect to the rejection of dependent claims 19-21 and 37-40 over Kieffer in view of Yabe '113 and further view of Moriyama, Appellants submit that neither Yabe '133 nor Moriyama cure the deficiencies of Kieffer. That is, Yabe '133 and/or Moriyama do not disclose or suggest a cover configured to be disposed on the tip of a probe end of an endoscope only when the endoscope is not in use, as recited by the claims. Accordingly, dependent claims 19-21 and 37-40 are each based on an allowable base claim. Therefore, Appellants respectfully request the Board to reverse the rejection set forth by the Examiner and allow dependent claims 19-21 and 37-40.

Conclusion

Appellants respectfully submit that all pending claims are in condition for allowance. However, if the Examiner or Board wishes to resolve any other issues by way of a telephone conference, the Examiner or Board is kindly invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,

Date: 5/21/2007


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8. **APPENDIX OF CLAIMS ON APPEAL**

Listing of Claims:

1. A cover for use with an endoscope, comprising:
a body having a recessed portion configured to releasably secure to an insertion portion of the endoscope and;
a disinfecting compound disposed thereon, wherein the body is configured to be disposed on the tip of the endoscope only when the endoscope is not in use.
2. The cover as recited in claim 1, wherein the recessed portion presents a tapered profile with respect to a longitudinal axis thereof.
3. The cover as recited in claim 1, wherein the body comprises an open cell foam.
4. The cover as recited in claim 1, wherein the body further comprises a channel coupled to the recessed portion such that the channel and recessed portion extend through the body.
5. The cover as recited in claim 1, further comprising an indicium indicative of a condition of the endoscope.
6. (cancelled).
7. (previously presented) The cover as recited in claim 1, wherein the disinfecting compound is integral to the body.
8. (previously presented) A cover for use with an endoscope, comprising:

a body having a recessed portion configured to releasably secure to a probe portion of the endoscope, wherein the body includes an indicium configured to indicate a condition of the endoscope, wherein the body is configured to be disposed on the tip of the endoscope only when the endoscope is not in use.

9. The cover as recited in claim 8, wherein the condition comprises a contamination condition.

10. The cover as recited in claim 8, wherein the indicium comprises a predetermined color.

11. The cover as recited in claim 8, wherein the indicium comprises a predetermined contour of the body.

12. The cover as recited in claim 8, wherein the condition comprises an operational condition.

13. The cover as recited in claim 8, wherein the indicium comprises information indicative of the manufacturer of the endoscope.

14. The cover as recited in claim 8, wherein the indicium includes a raised surface with respect to an external surface of the body.

15. (previously presented) An endoscope system comprising:
an endoscope comprising:
a light source configured to produce a light beam; and
a flexible conduit having a probe end and configured to receive the light beam from the light source, wherein the flexible conduit is configured to direct the light beam outwardly with respect to the probe end; and

first and second cover members each having a recessed portion configured to releasably secure to the probe end, wherein the first cover member comprises a first indicium indicative of a first endoscope condition and the second cover member comprises a second indicium indicative of a second endoscope condition, wherein the first and second cover members are configured to be disposed on the tip of the endoscope only when the endoscope is not in use.

16. The endoscope system as recited in claim 15, wherein the first and second indicia respectively comprise first and second predetermined colors representative of a sterile endoscope condition and a contaminated endoscope condition.

17. The endoscope system as recited in claim 16, wherein the first color comprises a green and the second color comprises a red.

18. The endoscope system as recited in claim 15, wherein the first and second indicia respectively comprise first and second cover member contours representative of a sterile endoscope condition and a contaminated endoscope condition.

19. The endoscope system as recited in claim 15, wherein the first and second cover members comprise an impact absorbing material.

20. The endoscope system as recited in claim 15, wherein the first and second cover members comprise an open cell foam.

21. The endoscope system as recited in claim 15, wherein the first and second cover members comprise a plastic material.

22. A method of covering a probe portion of an endoscope, comprising:
securing a first cover member having a first indicium indicative of a first endoscope condition to the probe portion;

removing the first cover member from the probe portion; and

securing a second cover member having a second indicium indicative of a second endoscope condition to the probe portion, wherein the first and second cover members are configured to be disposed on the tip of the endoscope only when the endoscope is not in use.

23. The method as recited in claim 22, wherein the first and second indicia respectively comprise first and second predetermined colors.

24. The method as recited in claim 22, wherein the first and second indicia respectively comprise predetermined first and second contours.

25. The method as recited in claim 22, further comprising sterilizing the probe portion prior to securing the second cover.

26. The method as recited in claim 22, wherein the first endoscope condition comprises a sterilized condition and the second endoscope condition comprises a contaminated condition.

27. An endoscope system, comprising:
an endoscope including a flexible conduit having a probe portion;
a first means for covering the probe portion, thereby indicating a first status of the endoscope; and
a second means for covering the probe portion thereby indicating a second status of the endoscope, wherein the first and second means are configured to be disposed on the tip of the endoscope only when the endoscope is not in use.

28. The endoscope system as recited in claim 27, wherein the first endoscope status is a sterilized status and the second endoscope status is a contaminated status.

29. The endoscope system as recited in claim 27, wherein the first and second means respectively comprise first and second predetermined colors.

30. The endoscope system as recited in claim 27, wherein the first and second means are detectable by touch.

31. A method of manufacturing a cover for a probe portion of an endoscope, comprising:

shaping a flexible synthetic material to form a cover configured to releasably secure to the probe portion; and

integrating with respect to the cover an indicium indicative of a status of the endoscope, wherein the cover is configured to be disposed on the tip of the endoscope only when the endoscope is not in use.

32. The method as recited in claim 31, wherein the indicium comprises a predetermined color.

33. The method as recited in claim 31, wherein the indicium is configured to be detectable by touch.

34. The method as recited in claim 31, wherein the flexible synthetic material comprises a plastic.

35. The method as recited in claim 31, wherein the flexible synthetic material comprises foam.

36. An endoscope cover system including an endoscope having an insertion portion, comprising:

a first cover having a first indicia indicative of a used state and a need for sterilization, the cover being configured to receive the insertion portion; and

a second cover having a second indicia indicative of a sterilized state, the second cover being configured to receive the insertion portion, wherein the first and second covers are configured to be disposed on the tip of the endoscope only when the endoscope is not in use.

37. The endoscope cover system as recited in claim 36, wherein the first and second covers comprise an open cell foam.

38. The endoscope cover system as recited in claim 36, wherein the first and second indicia include colors.

39. The endoscope cover system as recited in claim 36, wherein the first and second indicia include contours.

40. The endoscope cover system as recited in claim 36, wherein at least one of the first and second covers is disposable.

9. **APPENDIX OF EVIDENCE**

None.

10. **APPENDIX OF RELATED PROCEEDINGS**

None.